ATTACHMENT 1

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations

SMDL #02-014

September 18, 2002

Dear State Medicaid Director:

This letter is to clarify issues related to supplemental drug rebate agreements and prior authorization of Medicaid covered outpatient drugs. A number of States have sought CMS approval of supplemental drug rebate agreements between a State and drug manufacturers with respect to Medicaid covered outpatient prescription drugs. Some of these States subject covered outpatient drugs to prior authorization as a means of encouraging drug manufacturers to enter into separate or supplemental rebate agreements for covered drugs purchased by Medicaid recipients.

Medicaid Supplemental Drug Rebate Agreements

States may enter separate or supplemental drug rebate agreements as long as such agreements achieve drug rebates equal to or greater than the drug rebates set forth in the Secretary's national rebate agreement with drug manufacturers, which is published at 56 F.R. 7049 (1991). The drug rebate statute, at section 1927(a)(1) of the Social Security Act (Act), provides that "the Secretary may authorize a State to enter directly into agreements with a manufacturer." Also, section 1927(a)(4) of the Act provides that any drug rebate agreement between a State and drug manufacturers and in effect on November 5, 1990, may constitute a rebate agreement in compliance with the statute if CMS determines that any such agreement "provides for rebates that are at least as large as the rebates otherwise required under this section." CMS accordingly believes that Congress intended that States that seek CMS approval under section 1927(a)(1) to enter directly into agreements with manufacturers must ensure that any such agreement will achieve drug rebates that are at least equal to the rebates set forth in the Secretary's rebate agreements with manufacturers.

We remind States that supplemental drug rebates must be "considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance" as required by section 1927(b)(1)(B) of the Act.

Prior Authorization Requirements Related to Supplemental Rebate Agreements

States may subject covered outpatient prescription drugs to prior authorization as a means of encouraging drug manufacturers to enter into separate or supplemental rebate agreements for covered drugs purchased by Medicaid recipients. Section 1927(d)(1)(A) of the Act permits States to subject any covered outpatient drug to a requirement of prior authorization as long as the State complies with the requirements set forth in section 1927(d)(5). A prior authorization program used to negotiate drug discounts for the Medicaid program is consistent with those provisions as well as the paramount purpose of the drug rebate provisions which is to reduce the costs to the Medicaid program for prescription drugs.

A prior authorization program does not need to comply with the requirements for restrictive formularies. The formulary provisions of section 1927(d)(4) were added to the drug rebate provisions in 1993 to give States additional authority to implement restrictive formularies. Congress passed paragraph (d)(4) expressly stating that "[a] prior authorization program established by a State under [section 1927(d)(5)] is not a formulary subject to the requirements of this paragraph." Furthermore, since concerns related to drug use, monitoring, waste, fraud or abuse are separately and independently addressed by the procedures authorized by sections 1927(d)(6) and 1927(g), a prior authorization program need not be limited to those concerns. The Act affords States broad authority and flexibility to implement a prior authorization program in order to secure cost savings for the Medicaid program.

The operation of a prior authorization program used to negotiate drug discounts for the Medicaid population is a significant component of a State plan. We would therefore expect that a State that does not currently have an approved prior authorization State plan amendment, and that seeks to undertake such a program, would submit to CMS for review a State plan amendment incorporating the program's prior authorization requirements, while simultaneously seeking CMS's authorization for its proposed separate or supplemental rebate agreement. A State that has an approved State plan amendment governing prior authorization requirements, but which seeks for the first time to use its prior authorization authority to negotiate drug discounts for the Medicaid program, must amend its State plan to refer to the separate or supplemental rebate agreement and submit its proposed rebate agreement for CMS authorization.

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* Of course, the formulary provisions of section 1927(d)(4) continue to apply if a State chooses to make judgments about the therapeutic advantages of a drug excluded from a formulary, and the State plan must permit coverage of any such drug pursuant to a prior authorization program that complies with section 1927(d)(5).

Non-Medicaid Supplemental Rebates and Medicaid Prior Authorization

A number of States secure prescription drug benefits, rebates, or discounts for non-Medicaid populations by linking such benefits to a Medicaid prior authorization program. The Act does not preclude States from negotiating prices, including manufacturer discounts and rebates for non-Medicaid drug purchases. However, the establishment of a prior authorization program for Medicaid covered drugs to secure drug benefits, rebates, or discounts for non-Medicaid populations is a significant component of a State plan and we would therefore expect that a State would submit such a program for CMS review under the State plan process. Similarly, the use of any pre-existing prior authorization program to secure drug benefits, rebates, or discounts for non-Medicaid populations would constitute a "[m]aterial change[] in State law, . . . policy, or in the State's operation of the Medicaid program" and we would therefore expect that a State would submit a plan amendment to CMS for review. (See section 430.12(c)(1)(ii) of the regulations.) In submitting such a State plan amendment, the State should be prepared to demonstrate through appropriate evidence that the prior authorization program will further the goals and objectives of the Medicaid program. A State could make such a demonstration by submitting appropriate evidence that its prior authorization requirement is designed to increase the efficiency and economy of the Medicaid program. A State could demonstrate that its prior authorization requirement furthers Medicaid goals and objectives by submitting appropriate evidence that the requirement sufficiently benefits the Medicaid population as a whole by making available to financially needy individuals medically necessary prescription drugs, thereby improving their health status and making it less likely that they will become Medicaid eligible.

If you have any questions regarding CMS policy relating to supplemental drug rebate agreements or prior authorization programs, please direct them to Larry Reed at (410) 786-3325 or Deirdre Duzor at (410) 786-4626.

Sincerely,

/s/

Dennis G. Smith
Director

cc:

CMS Regional Administrators

CMS Associate Regional Administrators
for Medicaid and State Operations

Lee Partridge
Director, Health Policy Unit
American Public Human Services Association

Joy Wilson
Director, Health Committee
National Conference of State Legislatures

Matt Salo
Director of Health Legislation
National Governors Association

Brent Ewig
Senior Director, Access Policy
Association of State and Territorial Health Officials

Trudi Matthews
Senior Health Policy Analyst
Council of State Governments

Jim Frogue
Acting Director, Health and Human Services Task Force
American Legislative Exchange Council

ATTACHMENT 2

MEDICAID DRUG REBATE PROGRAM Release No. 14

*** * * IMMEDIATE ATTENTION REQUIRED * * ***

NOTE TO: All Participating Drug Manufacturers

STAGES OF THE DISPUTE RESOLUTION PROCESS

Stages of the Dispute Resolution Process (Attachment A), has been designed to provide general guidelines and time-limits associated with the dispute resolution process. We still stress the importance of open communication between both parties and keeping the Regional Office Drug Payment Coordinators involved.

EFFECT OF ADMINISTRATIVE FEES ON AVERAGE MANUFACTURER PRICE (AMP) AND BEST PRICE

Recently, we have received numerous inquiries from various manufacturers or their representatives requesting guidance on whether administrative fees paid to buyers of covered outpatient drugs have any effect on AMP and/or best price calculations. We consider administrative fees, incentives, promotional fees, chargebacks and all discounts or rebates, other than rebates under the Medicaid drug program, to be included in the calculation of AMP, if those sales are to an entity included in the calculation of AMP, and best price.

Except for the explicitly listed exclusions in the rebate agreement and in section 1927 of the Social Security Act, and, in accordance with sections I(a) and I(d) of the rebate agreement, AMP and best price data "... must be adjusted by the Manufacturer if ... other arrangements subsequently adjust the prices actually realized." Thus, we consider any price adjustment which ultimately affects the price actually realized by the manufacturer as "other arrangements" and, as required by the rebate agreement, included in the calculations of AMP and best price.

Please remember that any prices which are nominal in amount, that is, less than 10% of the AMP in the same quarter for which the AMP is computed, are excluded from the best price calculation. Therefore, if any arrangement results in prices which are nominal, those sales and prices do not affect best price and must be excluded by the manufacturer.

NOTICE TO HCFA OF REVISED AVERAGE MANUFACTURER PRICE (AMP) CALCULATION METHODOLOGY

Several drug labelers have notified HCFA of their intent to recalculate the AMPs for selected drug products. In those situations where you plan to submit revised AMPs and are changing the method by which you calculate the AMPs, contact HCFA prior to submitting revised AMPs to explain why you are recalculating the AMPs, the magnitude of the changes, the rationale being used, documentation to support the changes and whether these changes will affect your AMPs both retroactively and prospectively. HCFA will review this documentation and decide whether the proposed change conforms to the statute and the manufacturer's agreement. Do not submit any recalculated AMPs until notified to do so by HCFA. All documentation should be submitted to:

Medicaid Drug Rebate Program
P.O. Box 26686
Baltimore, MD 21207-0486

UNIQUE MEDICAID FACTORS TO BE CONSIDERED BY DRUG LABELERS IN REBATE DISPUTES

From the beginning of this program, HCFA has called upon the expertise of State Medicaid officials in trying to solve problems that occur periodically. This group of State officials referred to as the Pharmacy Technical Advisory Group (P-TAG) have provided information and help on numerous occasions. Recently, the members of the P-TAG developed a list of factors unique to State Medicaid drug programs that may help to reduce the number of rebate disputes by promoting a better understanding by the drug companies.

These factors include:

- Medicaid data includes nursing home dispensing data. Possibly, that information may not be included in manufacturer marketing data;

- Regional marketing data of manufacturers may fail to take into account any border pharmacies, chain drug store distribution systems or regional and national buying groups;

- Prescription limits (e.g., 3 per month) can result in large quantities dispensed per prescription, legitimately;
- Ingredients of compounded prescriptions billed by NDC may be claimed for rebates;
- The total amount reimbursed for prescriptions is not a reliable indicator of units dispensed since copayments, third party liability and sale pricing (loss leaders) can all reduce the total amount reimbursed;
- Topical prescriptions do not always represent one tube per prescription;
- State front end claim edits for maximum quantities must be known by manufacturers since without them, unusual quantities may appear on claims;
- Drugs the manufacturer may not consider outpatient drugs may be claimed for rebate when separate drug claims were generated and paid by the States (e.g. injectables);
- Outside data sources may not be infallible as to accuracy;
- Sales data may fail to reflect all sales to wholesalers or individual manufacturer's return/substitution policies may not be reflected in sales data but do affect actual inventory at the pharmacy;
- Conflicts regarding billing units still exist between the States, HCFA, First DataBank and MediSpan. This has caused a certain amount of under/over reporting by States;
- Manufacturers need to explain why an NDC is not valid (e.g. expired product);
- Manufacturers should know the States' unit dose policies and how they might impact rebate claims;
- Medicaid population as a percent of total State population is not a reliable indicator of Medicaid drug utilization;
- All States have a period of time, sometimes up to a year, from the date of service of a claim in which it can be submitted for payment; (e.g. Manufacturer sales in a quarter may not be indicative of Medicaid claims paid in a quarter); **and**

- The rebate invoices you receive from States are reflective of the claims **paid** during that calendar quarter **not** the number of claims dispensed to Medicaid patients.

WEEKLY U.S. TREASURY BILL DISCOUNT RATES

Attached is the latest listing of the 90-day treasury bill auction rates from January 3, 1994 through December 19, 1994. These rates are to be used to calculate interest owed States on overdue rebates.

TOPIC INDEX

For your convenience, also attached is a topic index of all items covered in prior releases.

Please continue to contact us with your drug rebate questions by using the Drug Rebate hotline at (410) 966-3249.

Sally K. Richardson
Director
Medicaid Bureau

3 Attachments

cc:

All Regional Administrators

All Associate Regional Administrators Division of Medicaid

Attachment A

THE MEDICAID DRUG REBATE PROGRAM
AND THE
STAGES OF THE DISPUTE RESOLUTION PROCESS

DISPUTE RESOLUTION PROCESS:

BEGINS: When the Manufacturer notifies State of disputed data, no later than 38 days after State utilization data is sent.

ENDS: When dispute is resolved and Manufacturer or State settles all disputed money amounts, including interest.

PHASE I: Exchange of Data Time Period:

Phase I of the process falls after the State receives the manufacturer's dispute and involves a period for both parties to seek resolution of dispute through exchange of information and informal negotiations. (The resolution of inconsistencies and the exchange of data should occur by the 38th day after State sends the utilization data.)

WHEN:	THEN:
By 60 days after the end of the quarter, State sends utilization data (invoice) to manufacturer. Manufacturer has 38 Days After Receipt of State Utilization Data (Invoice) to:	
A. Mfr. edits State data & resolves data inconsistencies with State	Mfr. distinguishes between data inconsistencies & disputes by examining such items as: -unit types, -units dispensed matches amount paid, -NDC numbers match Mfr. numbers, -incorrect decimal position.
NOTE: This process can be initiated through telephone contact with State. If State gives written or telephone confirmation, resolution is recorded by the manufacturer. However, if this resolution has not been completed by the 38th day after State sends utilization data, the dispute resolution process applies.	
B. Mfr. Agrees with invoice	Mfr. pays full rebate--process ends.
C. Mfr. considers cost effectiveness	Items that would have been disputed may be resolved if Mfr. considers it not cost effective to dispute.

WHEN:		THEN:
D.	Mfr. pays partial rebate & disputes some data	-Mfr. submits documentation necessary to identify, by NDC, the reason why data are disputed (written notice of dispute & check must be postmarked by the 37th day after the State data are sent. Interest starts on disputed portion of invoice effective 38 calendar days from the date the State mails the State utilization data.
Within 90 days after receipt of manufacturer's dispute:		
E.	State contacts Mfr. to discuss, by NDC number, items disputed & reason	State contacts Mfr. by telephone to discuss dispute. State presents report of preliminary response to dispute resolution.
Within 150 days after receipt of manufacturer's dispute:		
F.	State takes steps to resolve questionable data (Manufacturer requests additional supportive documentation from State)	State provides: -Zip-code level data, -Pharmacy level data, OR -Opt to conduct sampling of pharmacy claims, -Data of historical trends. Note: Type of data provided by State must match type of data requested by Mfr.
F.1.	Both parties unable to resolve differences	-Mfr. requests State to perform random sample of pharmacies, -State requests Mfr. to validate data used by third party for the purpose for which the manufacturer supplied it.

NOTE: States will ensure any exchange of data protects the confidentiality requirements of section 1927(b)(3)(D) of the Social Security Act. In the case of pharmacy level data, the State may request the Mfr. supply its data if confidentiality laws prevent State release of information.

Within 240 days after receipt of manufacturer's dispute:

	WHEN:	THEN:
G.	State considers cost effectivessness	If the exchange of information fails to remove dispute, and the disputed amount is BOTH -under $10,000 per Mfr.'s labeler code, AND -under $1,000 per product code of Mfr.'s labeler code (at 9-digit NDC level) the State may choose to cease the dispute process. NOTE: State maintains discretion to enter into the dispute process in cases that fall below these thresholds.
H.	State/Mfr. complete good faith negotiations	Settlement can be made on: -State utilization data, (State should document incorrect data) OR -Valid documentation that other data was acceptable.
I.	State/Mfr. unable to reach agreement.	The formal review processes are considered in Phase II of the Dispute Resolution Process. The State and Mfr. must proceed to Phase II - Formal Review Process

PHASE II: Formal Review

Phase II of the process is initiated when the dispute is not resolved and when all steps in Phase I have been completed. A State or a manufacturer may proceed to phase II if either party has not fulfilled its obligations under a step in the first phase of the process.

Within 30 days from the end of Phase I process the State must schedule a hearing that must be conducted no later than one year from the 240th day after the State receives manufacturer's dispute. The State and Manufacturer may continue to attempt to settle disputes before the hearing is conducted by considering the settlement options described below.

	WHEN:	THEN:
A.	Mediation Review Process in which mediator assists parties in reaching their own settlement but does not have authority to make a binding decision	-Both parties sign agreement to mediate, -Request for mediation prepared with brief statement of dispute, +Both parties agree on how to share mediation expense, +Qualified mediator selected, +Both parties agree on mediator, +Mediator will have no financial or personal interest in result of mediation, +Agreement reached, +Both parties sign settlement agreement, +Agreement states settlement & payment of mediation expense, +Amount in dispute paid plus interest due, +Mfr./State records documented, +Agreement not reached, +Both parties declare in writing that mediation ended, +Parties pursue Binding Arbitration or State Hearing.

	WHEN:	THEN:
B.	Non-Binding Arbitration Process in which each party presents its case at an informal hearing to a neutral party	-Both parties agree to participate in arbitration by submitting an informal request to the other party, -Parties agree on share of arbitration fee, -Both parties agree on arbitrator-Decision reached & settlement agreed by both parties, -Agreement states settlement and payment of fees, -Final decision subject to confirmation at a higher State Agency level, -Amount in dispute paid including interest, -Mfr./State records documented, -Agreement not reached, -Parties agree on share of arbitration fee, -Parties pursue Binding Arbitration or State Hearing.

	WHEN:	THEN:
C.	Binding Arbitration Process in which a dispute is submitted to one or more impartial persons for a final and binding decision	-Both parties agree to participate in arbitration, -Both parties agree on arbitrator or panel, +Arbitrator could be panel of individuals agreed to by the State agency & Manufacturer, +Arbitrator could be independent arbitration association.e.g., American Arbitration Association, -Settlement agreed by both parties, -Award submitted by arbitrator stating relief and arbitration fees, -If arbitration panel consists of more than one arbitrator the majority decision is binding.

	WHEN:	THEN:
D.	Administrative Review Upon request by either party for a hearing, an administrative review would be conducted by an impartial individual or panel appointed or hired as a hearing officer to facilitate settlement. This review would occur while State Hearing date is being scheduled. If agreement reached, State hearing would be cancelled.	-State requests date for State hearing, -Administrative Review scheduled prior to hearing, -Hearing officer appointed for Administrative Review, -Settlement reached at administrative review level, +Amount of rebate paid plus interest. +Settlement documented, +Request for State hearing cancelled -Agreement not reached at Administrative Review level, +Parties proceed to a State hearing which was scheduled prior to Admin. Review.

State Hearing must be conducted no later than one year from the 240th day after State receives Manufacturer's dispute.

E.	State Hearing State will make available its State hearing mechanism as defined in the statute and State law	-Hearing Held -Decision rendered -Dispute resolved -Rebates+interest pd. -Records documented

OPTIONAL ALTERNATIVES

The following option falls outside of the dispute resolution process, however, the National Rebate Agreement provides the following as an alternative States may pursue after receipt of manufacturers written dispute.

WHEN:	THEN:
Mfr. & State unable to resolve dispute	State may schedule an administrative hearing or tentatively schedule a hearing.
Mfr. & State agree on resolution. Mfr. pays rebate due but not interest due.	State tracks interest due and follows up with Mfr. Interest starts accruing on unpaid interest.

Phase I of the Dispute Resolution Process describes the type of data Manufacturers may request and States may provide in an attempt to resolve a dispute. Excluded from this level of the dispute process would be audits, i.e, fraudulent claims and claims level data requests. An audit may be pursued at any time throughout the dispute resolution process.

WHEN:	THEN:
CLAIMS DATA AUDITS	
-Manufacturer requests audit of State utilization data	-State, with appropriate Manufacturer input, develops mutually agreeable audit procedures
-Manufacturer requests pharmacy claims level data	-State agrees to audit pharmacy -State has independent third party audit pharmacy -Payment for audit determined between parties.
-Audit indicates either State utilization was greater or less than previously specified or information inaccurate	-Adjustments to rebates made -Dispute ends
-After audit performed, State and Manufacturer still in dispute	-Dispute still exists -Proceed to Phase II

DMcCarthy: x63314, MFRLTR14.